Application for Lower Facial Fat Reduction and Tightening by Static Type Monopolar 1-MHz Radio Frequency for Body Contouring

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Introduction: Liposuction and mesotherapy are popular treatments for fat reduction of lower face, but because these treatments are invasive, a novel non-invasive treatment with similar or better efficacy has been sought. There are various devices such as CoolSculpt, laser, RF, and HIFU that are used as non-invasive treatments for fat reduction and body contouring, but these applications have not been applied to facial fat reduction. In this study, we selected Monopolar 1-MHz RF for body contouring to be applied for fat reduction and tightening of the lower face.

Material and Methods: From March through August of 2016, we treated fourteen Asian women (average age: 44.6 years old) for fat reduction and tightening of the lower face using 1-MHz Monopolar RF (truSculpt™, Cutera, Inc., Brisbane, CA). We performed the treatment primarily in the nasolabial fold and buccal area weekly for five consecutive weeks, and evaluated the effects for fat reduction and tightening before each treatment and for 2 months after the treatment using handy VECTRA 3D® (Canfield Scientific, Inc.) for imaging. Three-dimensional (3D) volumetric assessments were performed at pre- and post-two-months after treatment. Patients rated their satisfaction for tightening using a 5-points scale.

Results: During the study, more than ninety percent of patients showed volumetric change by fat reduction at the treated area, with an average of 2.7 ml. Sixty percent of patients were either "satisfied" or "very satisfied" with the tightening effects. The treatments were accompanied only by very mild heat pain. Efficacy was maintained for 2 months after the treatments, and three patients showed a higher fat reduction effect at 2 months after the final treatment compared with the final treatment. A mild redness was observed just for few hours after the treatment, but complications such as, swelling, induration, burn, sensory disturbance or facial paralysis, were not observed.

Conclusion: In this study, we found that Monopolar 1-MHz RF applied with a stationary applicator was effective especially for lower face fat reduction and with a tightening effect in facial contouring. A highly efficacious treatment with satisfactory comfort and safety can be achieved with no downtime, and the device has the potential for becoming one of the standard non-invasive treatments for fat reduction of facial contouring. Lasers Surg. Med. © 2017 Wiley Periodicals, Inc.

Key words: fat reduction; tightening; facial contouring; radio frequency

INTRODUCTION

Liposuction and mesotherapy have been generally used to treat excessive subcutaneous fat and buccal fat in the lower face [1–3]. However, although liposuction is known to be an effective treatment, it is invasive and presents significant downtime due to post-procedure swelling and bruising [4]. Mesotherapy is also described to be effective in fat reduction, but requires multiple injections and is associated with post-procedure swelling and bruising [5–7]. A treatment with reduced recovery time and decreased risk of swelling and bruising is needed to treat the face [8]. Devices such as laser, RF, and HIFU, have been popular when used as a non-invasive treatment for facial rejuvenation, but they are not sufficiently effective for fat reduction of the lower face. There are various devices for fat reduction such as, CoolSculpt, laser, RF, and HIFU for

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body contouring [8,9], but these devices have not been utilized specifically for facial fat reduction. Unlike lasers, which rely on specific chromophores for absorption and are typically absorbed by specific tissues, RF is not tissue specific and enables heating of deep tissues safely and efficiently [9]. Also, RF has a tightening effect on the skin by increasing collagen production of the dermis and has a fat reduction effect when applied to subcutaneous tissues.

In general, an electromagnetic plane wave is exponentially attenuated as it propagates into tissue. At high frequencies or small wave lengths (e.g., laser light at 2.48×10^{19} Hz frequency or 1,210 nm wavelength), the power is transferred rapidly near the surface, attenuating the wave as power is taken out of it. Since the wave is highly attenuated deeper into the tissue, there is no energy left to extract from it. At lower frequencies (e.g., radiofrequency [RF] waves at 10^6 Hz or 150 m wavelength), the penetration depth is greater since the wave length is large and consequently, heating cannot be localized to restricted regions-hence, the term "bulk" tissue heating [10]. RF technology offers unique advantages for non-invasive selective heating of relatively large volumes of subcutaneous fat, due to its deep penetration into tissue. It then follows that relatively large volumes of fat can be heated with a monopolar device.

Monopolar 1-MHz RF (truSculpt™, Cutera, Inc., Brisbane, CA) is a fat reduction device for chin and body contouring, and is capable of creating a constant temperature in the treatment area tissue. This device has been developed based on the findings of Franco et al. whereby the viability rate of adipocyte cells was decreased to forty percent when subcutaneous fat was heated *in vivo* at 45°C for 3 minutes [11]. As such, this device is not a motion type RF applicator, but is a static non-moving type RF device that maintains a constant temperature for a preset time, with the skin temperature measured by a stamp RF applicator, and delivers energy to a specific treatment area, which lowers the viability of adipocyte cells to gradually induce a delayed adipocyte cellular death response in about 1 month after the treatment. The device has two applicators which can be chosen in accordance with the size of the treatment area. Generally, the larger applicator is used for the body, while the smaller applicator is for the treatment of smaller areas such as, the chin and the upper arm. Similar to previous clinical experience in which this device was effective in fat reduction of the chin area without complications, we attempted to apply this device to fat reduction and tightening of the lower face area.

MATERIALS AND METHODS

From March through August of 2016, we treated fourteen Asian women (average age: 44.6) for fat reduction and tightening of lower face using Monopolar 1-MHz RF. The treatment was conducted primarily in the nasolabial fold and buccal area with obvious subcutaneous and buccal fat. Using palpation, we excluded the area immediately beneath the subcutaneous fat such as, the malar bone and the edge of mandibular bone, to avoid the risk of stamping burns. The treatment was overlapped by fifty percent at the target area, as in Figure 1. Radiation time per stamp was set at 4 minutes, with three stamps on each side, for a total of six stamps for the entire lower face. The maximum temperature range was $43.5 \sim 46$°C; adjustments were made within the range in response to individual heat pain. We performed the treatment weekly for five consecutive weeks, and facial images were taken for evaluation of fat reduction and tightening before and after each treatment and at 2 months after the final treatment. Evaluation of treatment complications was conducted at each treatment and 2 months after the final treatment. To minimize the change in facial contour due to physical weight, the investigation was limited to patients whose change in weight during the study period was within 500 g.

Objective Assessment

3D imaging was performed by using handy VECTRA 3D® (Canfield Scientific Inc., Fairfield, NJ). This system is designed to accurately capture the surface shape and two-dimensional (2D) color information of the human face. A superimposed 3D color schematic representation indicates the volumetric changes in the face between pre-treatment and 2 month after last treatment, and shows the varying degrees of fat reduction and tightening in colors that ranges from yellow to red. Green areas indicate no change to the face. The volumetric changes were measured in

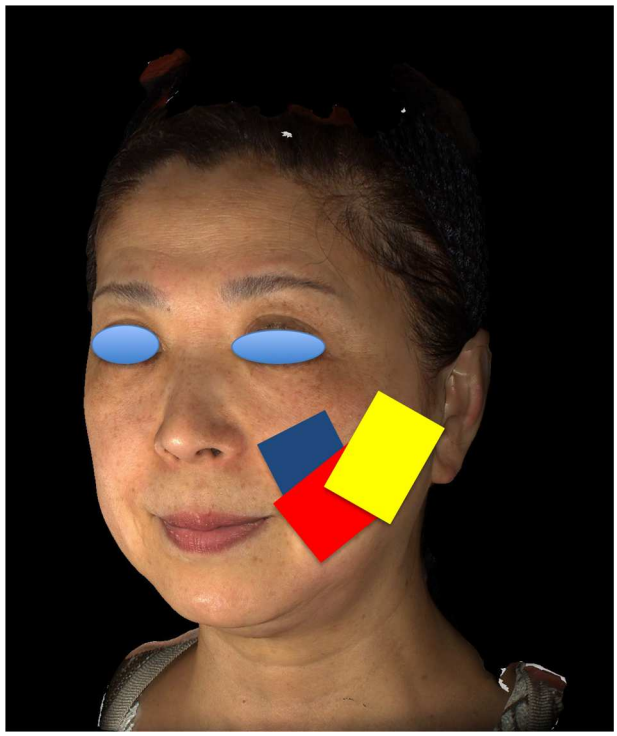

Fig. 1. Each stamp is overlapped by about 50%. Dark blue is the first stamp, red is the second stamp and yellow is the third stamp.

millimeters based on pre- and post-treatment photographs. To measure the specific treatment area, volumetric change was evaluated for the area within the nasolabial fold, marionette line, lower face line, anterior line of the ear and the base of nasal ala (Fig. 2).

Subjective Assessment

Subjective patient's assessments were performed using questionnaires in which the patients were asked to rate their degree of satisfaction in terms of tightening effect by this treatment based on a five-point scale ranging from 0 to 4 (0 = worse, 1 = not satisfied, 2 = fairly satisfied, 3 = satisfied, 4 = very satisfied). Questionnaires were completed 2 months after the final treatment.

RESULTS

During the study period, all patients maintained the change in their body weight within 500g. In most cases, the first treatment was conducted at 43.5°C. As a result of patients' reported heat pain levels, the temperature was raised to 45°C from the second treatment onwards.

Objective assessments evaluated with a superimposed Vectra 3D color schematic representation showed a volumetric change from fat reduction after the treatment in 92.9% of the cases, with an average of 2.7 ml (Fig. 3). Representative 2D color and superimposed 3D color images are shown in Figures 4 and 5. Tightening effects from fat reduction at the treated area can be identified in the representative 2D color images. In three cases, as shown in Figure 4, the fat reduction effect was even higher at 2 months after the final treatment. The mean degree of

Fig. 2. Light green area within the nasolabial fold, marionette line, lower face line, anterior line of the ear and the base of nasal ala is the area measured for the volumetric change by this treatment.

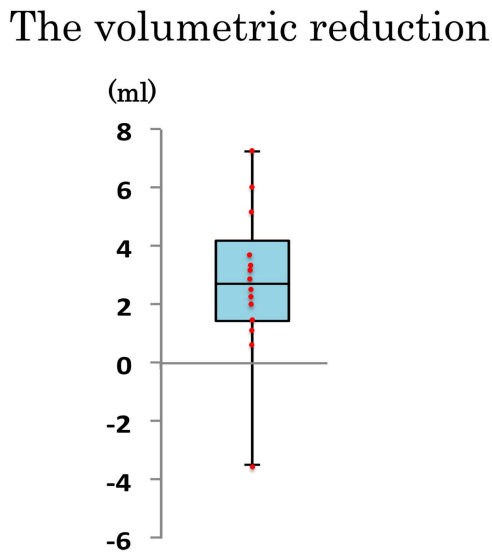

Fig. 3. The median volumetric reduction (ml) at 2 months post-treantment. The box illustrates the interquatile range (IQR) extending from the 25th percentile to the 75th percentile with a line placed at the median (50th percentile). The bottom and top end whiskers show the minimum and maximum data points, respectively. Volumetric reduction data for all cases are represented by the red dots.

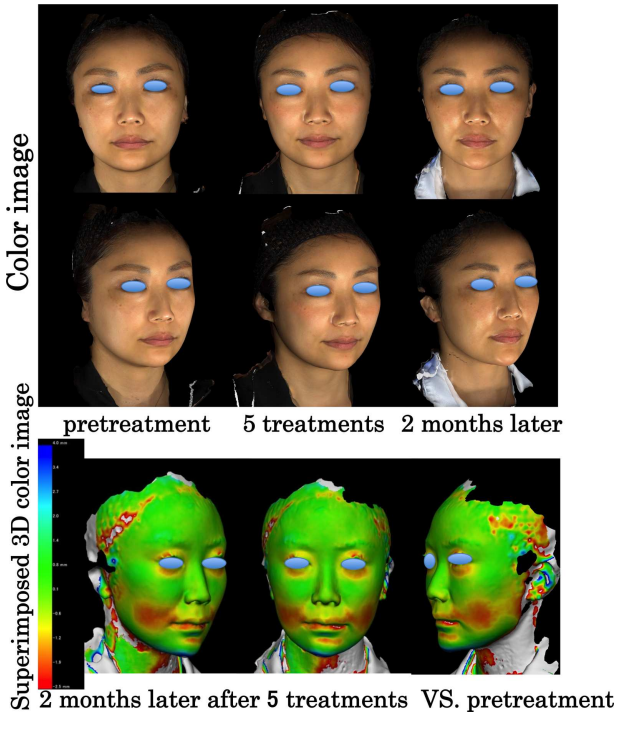

Fig. 4. A 36-year-old Japanese female. Images from left to right show the appearance before treatment to 2 months after 5 treatments. Panels from top to bottom show 2-D color and superimposed 3D color images. The varying degrees of tightening that were achieved are shown in colors ranging from yellow to red. Green areas indicate areas that remained unchanged.

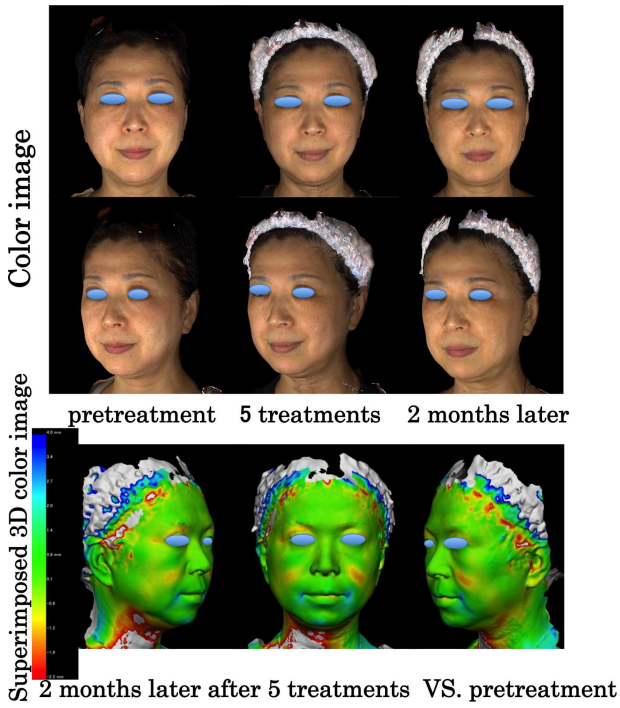

Fig. 5. A 62-year-old Japanese female. Images from left to right show the appearance before treatment to 2 months after five treatments. Panels from top to bottom show 2-D color and superimposed 3D color images.

satisfaction in terms of tightening effect based on a five-point scale from 0 to 4 was 2.6 ± 0.8 (Fig. 6).

Mild redness was observed just for few hours after the treatment, but complications such as, swelling, induration, burn, sensory disturbance or facial paralysis, were not observed.

Case 1

A 36-year-old female visiting the hospital complaining of excess fat in the lower face. The temperature of the first treatment was set at 43.5°C and thereafter at 45°C. The treatment was performed weekly for a total of 5 weeks, and there was an obvious fat reduction and tightening effect on the lower face after the treatment and fat reduction progressed at 2 months after the final treatment compared with the final treatment. In this case, there was a fat reduction of 5.3 ml, and the patient's subjective assessment was "very satisfied" (Fig. 4).

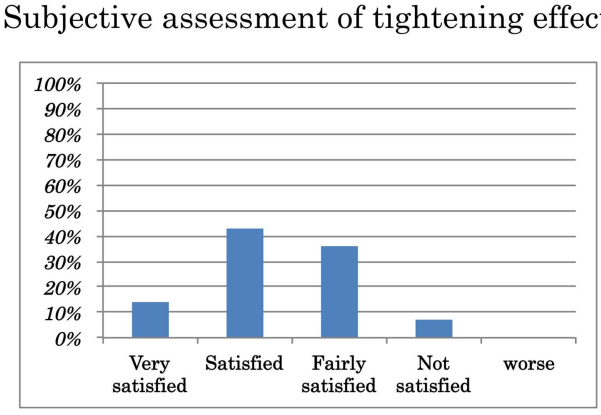

Fig. 6. Subjective satisfaction in terms of tightening effect at 2 months post-treatment.

Case 2

A 62-year-old female, visiting the hospital complaining of excess fat in lower face and sagging skin. The temperature of the first treatment was set at 44°C and thereafter set at 45°C. Treatment was performed weekly for a total of 5 weeks, and there was an obvious fat reduction and tightening effect on the lower face after the treatment and we could observe that the effect was still maintained 2 months after the treatments. In this case, there was a fat reduction of 0.8 ml, and the patient's subjective assessment of tightening effect was "satisfied" (Fig. 5).

DISCUSSION

The inherent advantage of this device design is the ability to provide uniform tissue heating across the entire surface of the applicator, as opposed to edge heating provided by ring-shaped and some solid type RF applicators. Uniform heating is achieved by controlling the distribution of the surface electric potential. Another major advantage of this device design is the ability to establish internal electric fields perpendicular to the skin—fat and fat—muscle interfaces, as shown analytically in Preferential Electric Heating of Fat Section, the strength of perpendicular internal electric fields results in significantly greater heating within the fat [11]. When perpendicular internal electric fields are established, the epidermis, dermis, and muscle are intrinsically protected from undesired power absorption [10]. The temperature at 12 mm depth is 2°C higher than the temperature of skin [11].

In this study, we observed that the treatment on the lower face using this device merely induced mild heat pain during the treatment without complications and with significant efficacy. The treatment resulted in both fat reduction and skin tightening. We further observed that these effects were maintained for several months after the treatment. Vectra 3D® used in this study provided a 3D reproduction enabling us to conduct a comprehensive analysis, which is generally not available using conventional 2D imaging. The evidence for objective assessment using Vectra 3D® for evaluation in facial rejuvenation and body contouring had been reported previously [12–14]. In this study, we identified the volumetric changes before and after the treatment using Vectra 3D®, which enabled us to objectively assess the efficacy of the treatment.

Generally, in aging people, there are symptoms such as, wrinkles, where skin tightening cannot compensate for the

loss of fat in the face due to decreased dermal thickness, decreased collagen production and progressive laxity of the retaining ligaments of the face. In using this device for fat reduction, there was no change or increase in wrinkles observed, while skin tightening and fat reduction were observed. Based on the volumetric fat reduction measurements and the highly "satisfactory" rating of the subjective skin assessment of the tightening effect, it may be that the device could induce not only fat reduction but also remodeling of the dermis.

In this study, we did not raise the temperature of the device to as high as 65°C, the temperature required for degeneration of the collagen protein, which indicates that the remodeling effect accompanying the promotion of collagen was possibly caused by acceleration of dermal fibroblast production. From these findings, we assess that the changes observed by use of this device are primarily associated with fat reduction, and that the tightening effect accompanying remodeling of the dermis is an additional effect. In some cases, we also recognized a change similar to face-lift. It is possible that the heating of subcutaneous tissue, with the peculiar characteristics of high frequency RF, enhances the flow of electric current between the adipose tissue to the retaining ligament, thereby causing tightening of the retaining ligament. Retaining ligaments, along with superficial musculo-aponeurotic system (SMAS), are believed to be structural elements that can affect sagging. Human face contains many retaining ligaments and symptoms such as, nasolabial fold and marionet lines, are considered as being caused by laxity of retaining ligaments [15–17]. These ligaments are primarily comprised of collagen, and it is possible that the tightening effect after RF could be caused by the promotion of collagen due to repeated heating process of this treatment. It is possible that a three-dimensional tightening phenomenon, including collagen of the ligaments, could be occurring along with the tightening effect of the dermis.

For fat reduction in the lower face, liposuction and mesotherapy, are popular treatments [1–3]. These methods are accompanied by complications such as pain, swelling, and bruising that are not desirable for facial treatment. An effective alternative treatment with reduced recovery time is required to overcome these problems. Treatment with the RF device used in this study will overcome these problems by providing a treatment with a minimal degree of heat pain and, although it requires sequential treatment sessions, is an effective treatment for fat reduction. Heat pain, as previously described, is felt in the first treatment at about 43°C [18–20], but it becomes painless and comfortable from the second treatment onwards even with the temperature raised to about 45°C.

Prior to this study, we conducted a preliminary trial of fat reduction treatment for facial contouring using this device. Similar to body contouring, we started with a once-a-month treatment but gradually shortened the intervals for better effects, resulting in the protocol that we have today. However, at the start of this study, there was a concern about the potential for excessive fat reduction to the extent of causing concavity at the irradiated area. In the basic research during the development stage of this device, it was determined that, by applying a uniform temperature of 45°C to the adipose tissue, approximately 60% of the adipose tissue will lose its viability after 1 month [11]. According to this basic research, if we were to conduct a weekly treatment for 5 weeks, we would be conducting the next treatment before the adipose tissue of the treatment area begins its delayed adipocyte cellular death response. Contrary to our concern, however, in this study where we limited the treatment to a maximum of five times, although fat reduction progressed in three cases 2 months after the final treatment, there was no excessive fat reduction to the extent of causing concavity in all cases even 2 months after the treatment. Although the reason for this finding is not clear, we believe that the risk for excessive fat reduction is clinically low and the treatment is extremely easy to tolerate. However, it is necessary to avoid excessive treatment which may cause excessive fat reduction, and due consideration must be given to the treatment intervals in line with the overall effects. Nevertheless, we think that this study using this device was extremely meaningful for having achieved adequate efficacy in overcoming the difficulties of a non-invasive fat reduction to the lower face with mild pain and without complications.

There was no complication observed in this study such as, burns, induration, pigmentation changes, sensory disturbance, or facial paralysis. However, it should be noted that a treatment immediately above the malar bone and the edge of mandibular bone should be avoided, since bones reflect high frequency waves and tend to accumulate heat easily. Heat applied at approximately 50°C is described to cause dermopathy [21,22], and although the temperature setting in this study is assumed to be safe, we should carefully consider patient-reported heat pain and to avoid carelessly raising the set temperature in pursuit of effective results, which in turn will increase the risk of burns. The RF device used in our study is a stationary type of applicator, as opposed to an applicator that applies energy as it is moved, and is relatively easy to handle [9]. We believe that it will prove to be a valuable and effective device for fat reduction and tightening of lower face without complication.

CONCLUSION

We found through this study that Monopolar 1 MHz RF applied with a stationary applicator can sustain a fixed therapeutic temperature and is very effective in fat reduction and tightening of the lower face. There was no complication nor downtime, and it is extremely safe and comfortable for patients. While there is a certain variation in the efficacy that needs to be further evaluated, the device

has a potential for becoming one of the standard non-invasive treatments for fat reduction of the facial contour.

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